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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,907	11/27/2001	Sheng-Ping Zhong	01-286	7678

27774 7590 07/14/2005

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,907	ZHONG ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-12,15-41,43,44 and 46-69* is/are pending in the application.

4a) Of the above claim(s) *39-41,43,44 and 46-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,15-38 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

Claims 1,3-8,10-12,15-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to disclose that the visibility of detectable species associated with the hydrogel polymer to MRI is modified by varying the degree of cross-linking.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by DiCosmo et al. DiCosmo et al disclose an insertable medical device comprising a substrate such as a catheter and a hydrogel coating disposed on the substrate. The hydrogel polymer can be cross-linked. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 3-5.

Claims 1,3-7,30,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne. Whitbourne discloses a medical device such as a catheter comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 3-7.

Claims 1,3-5,10-11,15-22,28-31,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 3-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. With respect to claims 16, 18, Weissleder et al disclose that the paramagnetic materials may be covalently bonded to the hydrogel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Michaels. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. Michaels discloses the use of a hydrogel coating that contains glycerin so as to prevent cracking during the drying process of the coating. It would have been obvious to one skilled in the art to have modified Weissleder et al such that glycerin is applied to the hydrogel to prevent cracking when the coating is applied to the medical device.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Klaveness et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 3-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. Weissleder et al fails to specifically disclose the use of starch-coated iron oxide particles. Klaveness et al disclose MRI detectable materials comprising starch-coated iron oxide particles. It would have been obvious to one skilled in the art to have modified Weissleder et al such that the paramagnetic particles used are starch-coated iron oxide particles. Such a modification involves the substitution of one known type of paramagnetic particles detectable by MRI for another.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Peng et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The

coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The hydrogel will inherently possess the properties as set forth in claims 3-5. The hydrogel composition can be cross-linked and can include paramagnetic particles/ions as set forth in the claims. Weissleder et al fails to disclose the use of aminopolycarboxylic acid. Peng et al disclose in paragraph 50 that aminopolycarboxylic acid is a know chelating agent for use with paramagnetic particles in MRI. It would have been obvious to one skilled in the art to have modified Weissleder et al such that it includes aminopolycarboxylic acid as the chelating agent for use with paramagnetic particles. Such a modification merely involves the substitution of one well known type of chelating agent for another.

Claims 24-27,32,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al in view of Cleary et al. Weissleder et al disclose a medical device comprising a substrate such as a catheter and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. Weissleder et al fails to disclose the use of acrylic acid. Cleary et al disclose hydrogel compositions that include substituted or unsubstituted acrylic acid, polyacrylic acid, and a copolymer of acrylic acid and acrylamide. It would have been obvious to one skilled in the art to have modified Weissleder et al such that the hydrogel composition is as taught by Cleary et al. Such a modification merely involves the substitution of one known type of hydrogel composition for another.

Claims 34,36-38,69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al. Weissleder et al disclose a medical device comprising a substrate such as a interventional medical device and a hydrogel polymer coating disposed on the substrate. The coating is used to be able to visualize the device in the patient. The coating will inherently, based upon its known properties, render the device visible under MRI when placed in a patient. The coating should provide a lubricious layer by itself once it contacts bodily fluids, however it would have been obvious to one

skilled in the art to have provided an additional layer to ensure that the coating exhibits lubricious properties upon entry into the patient to prevent harm from coming to the patient as such is a well known expedient in the art. With respect to claims 36-38, it would have been obvious to one skilled in the art to have applied the coating to any type of device placed in the body for which one needs to monitor its location. With respect to claim 69, applicant discloses that it is known to use a primer coating to enhance adherence of a hydrogel polymer to a substrate. It would have been obvious to one skilled in the art to have modified Weissleder et al such that a primer coating is first applied in order to enhance adherence of the polymer to the substrate as taught by the prior art.

Response to Arguments

Applicant's arguments filed 5/2/05 have been fully considered but they are not persuasive. The recitation regarding the device being visible under MRI is directed to the intended use of the device and does not add any structural limitations to the device being claimed. Furthermore, the language set forth on lines 6-8 of claim 1 is directed to and intended process limitation and does not add any further structural limitations to the claim. With regard to the new matter rejection set forth, the portions of the specification referred to by the applicant fail to disclose the limitations as now set forth in claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

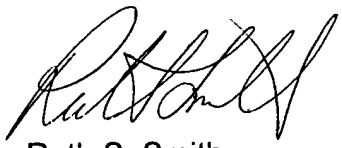
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS